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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/825,992	04/05/2001	Nurhan Pinar Tutuncu	2280.2660	3697
5514	7590	09/29/2004	EXAMINER	
FITZPATRICK CELLA HARPER & SCINTO 30 ROCKEFELLER PLAZA NEW YORK, NY 10112			GOLLAMUDI, SHARMILA S	
			ART UNIT	PAPER NUMBER
			1616	

DATE MAILED: 09/29/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>
	09/825,992	TUTUNCU ET AL.
	<b>Examiner</b>	<b>Art Unit</b>
	Sharmila S. Gollamudi	1616

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

1) Responsive to communication(s) filed on 12 July 2004.

2a) This action is **FINAL**.                            2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

4) Claim(s) 1-8 and 10-27 is/are pending in the application.

4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.

5) Claim(s) \_\_\_\_\_ is/are allowed.

6) Claim(s) 1-8 and 10-27 is/are rejected.

7) Claim(s) \_\_\_\_\_ is/are objected to.

8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) All    b) Some \* c) None of:

- Certified copies of the priority documents have been received.
- Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
- Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

1)  Notice of References Cited (PTO-892)

2)  Notice of Draftsperson's Patent Drawing Review (PTO-948)

3)  Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_

4)  Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_

5)  Notice of Informal Patent Application (PTO-152)

6)  Other: \_\_\_\_\_

## DETAILED ACTION

Receipt for Request for Continued Examination received on July 12, 2004 is acknowledged.

Claims **1-8 and 10-27** are pending in this application. Claim 9 stands cancelled.

### *Response to Arguments*

Applicant's arguments with respect to claims have been considered but are moot in view of the new ground(s) of rejection based on the amendments.

### *Claim Rejections - 35 USC § 112*

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

**Claims 6 and 23 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.**

Claim 6 and 23 respectively recite "monosodium glutamate enhancers" and "salt enhancers", which is vague and indefinite. It is unclear what exactly monosodium glutamate enhancers and salt enhancer are. Further, clarification is requested.

*WHAT ABOUT  
cooling  
comps?*

### *Claim Rejections - 35 USC § 102*

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

((e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

**Claims 1-3, 6-8, 15-18, and 20-27 are rejected under 35 U.S.C. 102(e) as being anticipated by US patent 6,231,900 to Hanke.**

Hanke discloses a confectionary product for soothing core through and relief of symptoms associated with cough and cold. The product is administered as a throat drop or lozenge which releases the actives upon sucking in the oral cavity. See abstract and column 1, lines 10-20. Hanke teaches the use of a separate and distinct region for a flavor composition and a cooling composition. The cooling agent taught is as any agent that provides a physiological cooling effect. See column 2, lines 55-57. Example 1 discloses the two separate compositions wherein A contains 97.8% of a sweetened gelatin (protein) mixture, 1.4% citric acid, and 0.6% of a flavor and B contains 99% of a sweetened gelatin mixture, 0.7% citric acid (acidulant), and 0.1 menthol (cooling compound). The gelatin mixture is made of gelatin, sucrose, and glucose. See example 1. Hanke discloses the use of a mold in which the respective composition is placed and each composition has a surface on the exterior of the product.

Note that the preamble is inherently met since the prior art discloses the instant method steps of administering a confectionary product containing two separate regions. Further, the prior art discloses the confectionary product relieves throat irritation, which is a symptom of xerostomia. Therefore, the instant method steps are not distinguishable over the prior art. Additionally, composition A reads on the oral comfort region since it contains gelatin and composition B reads on the salivation region since it contains an acidulant and cooling compound.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

**Claims 1-8, 10, 13-14, 17, 20, and 22-26 are rejected under 35 U.S.C. 102(b) as being anticipated by EP 0150934 to Cherukuri et al.**

Cherukuri et al disclose a multi-layered chewing gum composition and a method of making such. The chewing gum comprises a first region a second region, and optionally other regions, wherein each region has a different composition. See abstract.

Example II discloses a two layer gum wherein the first region contains: 17% gum base, 0.5% malic acid (acidulant), 17% corn syrup, 1% liquid orange flavor, 0.5% powdered orange flavor, 0.25% citric acid (acidulant), 0.2% color, 0.2 lecithin, 0.4% glycerin, and 63% sugars and the second region contains: 17% gum base, 17% corn syrup, 1% liquid pineapple flavor, 0.5% powdered pineapple flavor, 0.2% color, 0.2 lecithin (oral comfort agent), 0.4% glycerin, and 63% sugars. The two sheets are pressed together to form a two-layer gum wherein both regions have a surface on the exterior of the product. Note the first layer is considered the salivation region and the second layer is considered the oral comfort region.

Table IV discloses a gum wherein the first region contains: 17% gum base, 0.5% malic acid, 17% corn syrup, 1.5% flavor, 0.25% citric acid 0.2% color, 0.2 lecithin, 0.4% glycerin, 60.24% sugars, and 1.353% coated ascorbic acid (acidulant). The second composition (region) and third composition contain the same components of region one except for the ascorbic acid. Note the first layer is considered the salivation region and the second/third layer is considered the oral comfort region. Cherukuri further discloses the use of diluents (xylitol, mannitol, and sorbitol) to make the composition.

Cherukuri discloses that the method of making the product is the same as conventional techniques known in the art. The gum, corn syrup, and lecithin are blended together for two

minutes at a temperature of 82-92 degrees Celsius. The remaining components are then added and heating is continued for about five minutes. The gum composition is then formed into sheets. See page 9.

Note that lecithin is known as a surfactant and a lipid in the art. Further, note that the preamble is inherently met since the prior art discloses the instant method steps of administering a confectionary product containing two separate regions. Further, the prior art discloses the confectionary product relieves throat irritation, which is a symptom of xerostomia. Therefore, the instant method steps are not distinguishable over the prior art.

**Claims 1, 6, 8, 10-13, 17, 20, 23-24, and 26-27 are rejected under 35 U.S.C. 102(b) as being anticipated by US patent 5,284,659 to Cherukuri et al.**

Cherukuri et al ('659) disclose encapsulated flavor with bioadhesive character in pressed mints and confections. The compressed tablet is characterized by a product that has discrete phases contained within. See Figure 5 and 6 wherein both phase 1 and 2 have a surface on the exterior of the product. Example 1 discloses a product wherein the shell component contains 97.676% sugar, 0.748 % of a breath deodorant (copper gluconate), 0.234% lubricant, 1.280% flavor beads, 0.062% liquid flavor and the core is a fat encapsulation containing 48% partially hydrogenated soybean oil, 5% glycerol monostearate, 10% vegetable oil, 2% flavor oil, and 20% bioadhesive. The tablet is made by mixing each respective composition with the respective components separately and the core is compressed into the shell portion. See column 10, line 40 to column 11, line 28.

Note that the preamble is inherently met since the prior art discloses the instant method steps of administering a confectionary product containing two separate regions. Further, the prior

art discloses the confectionary product relieves throat irritation, which is a symptom of xerostomia. Therefore, the instant method steps are not distinguishable over the prior art. The shell portion reads on the salivation region since it contains flavors and a salt (copper gluconate) and the core reads on the oral comfort region.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

**Claim 19 is rejected under 35 U.S.C. 103(a) as being unpatentable over US patent 6,231,900 to Hanke (6231900) in view of US patent 6,099,880 to Klacik et al.**

As set forth above, Hanke discloses preparation of a confectionary product to relieve cough containing a separate and distinct region for a flavor composition and a cooling composition. Hanke discloses the use of a mold in which the respective compositions are placed. (Note example 1)

The reference does not teach a mold having a ridge to separate the components.

Klacik et al discloses a patterned candy containing agents such as sugar, sugar alcohol, coconut oil, and flavors. Klacik et al teach the mold having separate region and depositing mixtures in each segment to form a product with visually distinct regions. Klacik teaches this method to be a simple method. See column 1, lines 30-50.

It is would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the Hanke and Klacik et al and utilize a mold with a ridge. One would have been motivated to do so since Klacik et al teach an economical and simple process of producing a product having distinct regions using a mold having a ridge. Therefore, it is obvious to utilize a ridge to further maintain the separation and distinction of each respective region.

*Conclusion*

No claims are allowed at this time.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sharmila S. Gollamudi whose telephone number is 571-272-0614. The examiner can normally be reached on M-F (8:00-5:30), alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz can be reached on 571-272-0887. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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